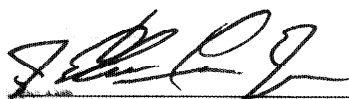


20 E. 69<sup>th</sup> St.  
Kansas City, MO 64113  
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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane - Room 1061  
Rockville, MD 20852

Comment to Docket Number 00D-1543

Reference Term	Comment
Computer Systems Validation	The definition is good. Rather than try to make the process validation definition fit where it is not appropriate. I suggest that the word "consistently" in the definition be replaced with "reliably". The term "consistently fulfilled" has some connotations in repetitiveness that may be unintended, particularly in systems that depend on configuration (or recipe) settings and dynamic process information to determine their exact behaviors.



J. Edward Crosson, Jr.

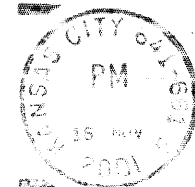
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Crosson  
20 E. 69<sup>th</sup> St  
Kansas City, MO 64113

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Food and Drug Administration  
5630 Fishers Lane Room 1061  
Rockville, MD 20852

Att'n: Comment to Docket 00D-1543



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